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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/567,498

03/02/2007

Michael Frass

FRZ-106US

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EXAMINER

STOUT, MICHAEL C

ART UNIT

PAPER NUMBER

4123

MAIL DATE

DELIVERY MODE

01/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,498	<b>Applicant(s)</b> FRASS ET AL.	
	<b>Examiner</b> MICHAEL C. STOUT	<b>Art Unit</b> 4123	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2,3,9-11 and 18-21 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2,3,9-11 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on February 7, 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. ____.                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>February 7, 2006</u> .  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Specification***

1. The disclosure is objected to because of the following informalities:
  - a. Page 12 Line 5 has the phrase "inner wall 1i" and should be corrected. Appropriate correction is required.

### ***Claim Objections***

2. Claims 2 and 3 are objected to because of the following informalities:
  - b. Claim 2 cites "a said stop means" which lacks sufficient antecedent basis "said" should be removed. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 2, 3, 9-11 and 21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 2, 3, 9-11 and 21 recites the limitation "the needles" in claim 18. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Bachynsky (US 5,971,953).

Bachynsky discloses a device for needle biopsy with a syringe cylinder (cylindrical section, 21, see Figure 1), with a plunger displaceable therein (lower piston 32) as well as with a needle means (Figure 1 shows the device having a needle means), wherein the needle means has at least one needle whose channel opens into the interior of the cylinder (Figure 1 shows the needle 18 having a channel which opens into the cylinder), and a ventilation means is formed by at least one overflow channel (Figure 2 shows an enlarged diameter section 25 with a plurality of overflow channels), which is formed at a distance from the syringe bottom in the inner wall of the cylinder (formed some distance from the needle end of the syringe, see Figure 1), wherein the length of the channel in the direction of the cylinder axis (see Figure 2) makes it possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel (see Figures 3-5).

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Gibbs (US 6,482,187 B1) .

Bachynsky fails to disclose the device in accordance with claim 18 wherein the needle means has a plurality of needles.

Gibbs discloses an injection device comprising a plurality of needles. Both Bachynsky and Gibbs teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a plurality of needles as taught by Gibbs in order to reduce trauma, see Column 8, Lines 55-59.

12. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Gibbs (US 6,482,187 B1) and Ferrell (US 3,552,394).

Bachynsky fails to disclose the device in accordance with claim 18 wherein the needle means has a plurality of needles and at least some of the puncture needles of the needle means have different lengths.

Gibbs discloses an injection device comprising a plurality of needles. Both Bachynsky and Gibbs teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a plurality of needles as taught by Gibbs in order to reduce trauma, see Column 8, Lines 55-59.

Ferrel teaches a syringe device comprising a plurality of needles (33 and 34) having different lengths, see Figure 2.

Both Bachynsky/Gibbs and Ferrell teach syringe devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the device taught by Bachynsky/Gibbs to include a plurality of needles having different lengths as taught by Ferrell in order to allow the needles to penetrate to varying skin levels in the patient, see Column 2, Lines 50-55).

13. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Ferguson (US 6,972,006 B2 and US2004/0054332A1).

Bachynsky fails to disclose the device in accordance with claim 18 wherein at least one indicator projection, which projects from the inner wall of the cylinder and can be overcome by the plunger, is provided at a distance from the bottom of the cylinder.

Ferguson teaches a syringe device comprising at least one indicator projection (tactile ridges, 333), which projects from the inner wall of the cylinder and can be overcome by the plunger (see Figure 3 and Column 5 Lines 29-54), is provided at a distance from the bottom of the cylinder.

Both Bachynsky and Ferguson teach syringe devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include indicator projections as taught by

Ferguson in order to provide useful tactile feedback to users who are rushed or in low lighting situations, see Ferguson Column 3, Lines 9-16.

14. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Gibbs (US 6,482,187 B1) and Erez et al. (US 6,290,683).

Bachynsky fails to disclose the device of claim 18 wherein the device has a stop means, which limits the depth of penetration of the needles into the body in a defined manner and Bachynsky further fails to teach the device wherein a spacer, which has holes associated with the needles and can be pushed over the needles in order to limit the depth of penetration into the body, is provided at least as a stop means.

Gibbs discloses an injection device comprising a plurality of needles. Both Bachynsky and Gibbs teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a plurality of needles as taught by Gibbs in order to reduce trauma, see Column 8, Lines 55-59.

Erez et al teaches a device wherein the device has a stop means (sleeve 32) which limits the depth of penetration of the needle into the body in a defined manner (see Figures 4a and 4b) and a spacer (sleeve 36 acts as a spacer), which has a hole associated with the needle (the needle has a hole 35 associated with it) and can be pushed over the needle in order to limit the depth of penetration into the body (Figure 4b



shows the device in a compressed state where the sleeve has been pushed over the needle limiting the device to a depth d), is provided at least as a stop means.

Both Bachynsky/Gibbs and Erez teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky/Gibbs to include a spacer stop means as taught by Erez in order to provide a means to control the injection depth of devices, see Column 5, Lines 34-44.

15. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Gibbs and Rieck (US 2,551,902).

Bachynsky fails to disclose the device for needle biopsy in accordance with claim 18 wherein a common protective sleeve, which can be attached by plugging to the syringe cylinder over the needles, is provided for all needles.

Gibbs discloses an injection device comprising a plurality of needles. Both Bachynsky and Gibbs teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a plurality of needles as taught by Gibbs in order to reduce trauma, see Column 8, Lines 55-59.

Rieck teaches an injection device comprising a common protective sleeve (sleeve 42, see Figure 2), which can be attached by plugging to the syringe cylinder over the needles (is frictionally mounted about the cup, see Figure 2 and Column 2 Lines 42-46), is provided for all needles.

Both Bachynsky and Rieck teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a protective cap over the needles as taught by Rieck in order to protect the device while being transported or handled, see Column 2, Lines 42-46.

16. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachynsky (US 5,971,953) in view of Gibbs and Ishikawa (US 3,757,780).

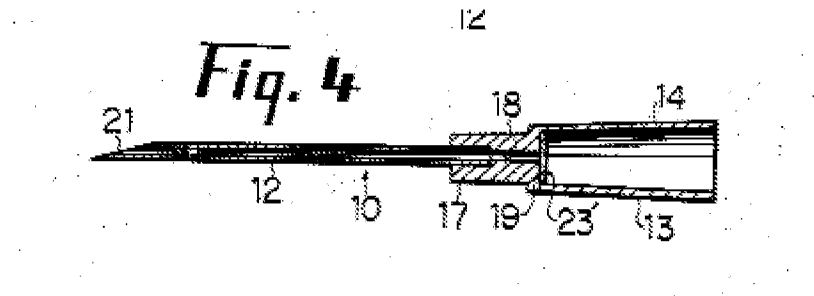
Bachynsky fails to teach the device for needle biopsy in accordance with claim 18 wherein a filter means is arranged in the path between the opening of the channels into the tips of the needles and the interior of the syringe cylinder, wherein the filter means comprises individual filter inserts in the tip-side end area of the needles.

Gibbs discloses an injection device comprising a plurality of needles. Both Bachynsky and Gibbs teach injection devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Bachynsky to include a plurality of needles as taught by Gibbs in order to reduce trauma, see Column 8, Lines 55-59.

Ishikawa teaches a device wherein a filter means (filter 23, see Figure 4) is arranged in the path between the opening of the channels into the tips of the needles and the interior of the syringe cylinder (see Figure 4), wherein the filter means comprises individual filter inserts in the tip-side end area of the needles (see Figure 4).

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Both Bachynsky and Ishikawa teach injection devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the device disclosed by Bachynsky to include an individual filter insert as taught by Ishikawa in order to remove contaminants from the ejection fluid, see Column 1, Lines 49 -53.



### **Conclusion**

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure and additional information on cited references can be found in Form 892.

### **Contact Info**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is

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(571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCS

/Essama Omgba/  
Primary Examiner, Art Unit 3726